

MALLEABLE INTRODUCER

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to endotracheal catheters, and more particularly to introducers for the intubation of such catheters into the patient. Specifically, the present invention is directed towards a malleable introducer tube having a smooth, inflatable sheath at its distal end.

2. Description of the Related Art

A wide variety of catheters are available to the practicing physician for intubation into the different passageways of a patient as the need arises. Catheters vary in size, length, type, and texture of material of which they are composed.

Of importance to the anesthesiologist is the class of catheter known in the art as endotracheal tubes designed for intubation into the trachea of a patient prior to anesthesia, in emergency situations such as those requiring resuscitation, and for life support. Endotracheal tubes may be of the cuffed or uncuffed type, the uncuffed type being a smooth, long, hollow, pliable tube having open proximal and distal ends. The conventional cuffed endotracheal tube is provided with an inflatable cuff or balloon surrounding the outside distal end portion of the tube at a position above the distal tip. The ends of the cuff are secured to the outside wall of the tube to provide a fluidtight seal between the outside wall and the inside of the cuff. After intubation of a cuffed tube, the cuff is expanded by applying air (or other non-toxic fluid) under pressure to ensure that the outside wall of the cuff embraces the trachea of the patient.

The distal tip, or end, of conventional catheters and endotracheal tubes is usually beveled at an angle which may vary between 30 to 60 degrees, depending, in part, upon the type of catheter to be used. In addition to the beveled distal tip, certain catheters and endotracheal tubes may have a small side or lateral opening through the side wall of the catheter at the distal end portion of the tube just above the beveled tip. This latter design is referred to in the art as a Murphy tip.

Intubation of the endotracheal tube, whether cuffed or uncuffed, may be accomplished either by inserting and passing the distal end portion through the patient's mouth and down into the trachea or, under certain conditions, by inserting and passing the distal end portion through the patient's nasal passageway past the pharynx and down into the trachea. In the former case, the endotracheal tube may be of a size and type identified as an oral endotracheal tube. Endotracheal tubes, identified as either oral or nasal, may be intubated through the mouth or through the nose of the patient.

The intubation of catheters and endotracheal tubes is not without its problems. To aid the intubation of oral endotracheal tubes, the anesthesiologist may employ a catheter guide or stylet inserted within the endotracheal tube prior to intubation to enable the physician to shape the endotracheal tube, provide additional structural rigidity to the tube, and afford an improved means for gripping and maneuvering the tube to accomplish intubation. My prior U.S. Pat. Nos. 3,957,055; 4,185,639; and 4,655,214 pertain to improvements in the intubation of catheters and endotracheal tubes. These patents are incorporated herein by this reference.

Due to the highly sensitive and delicate nature of the mucous membranes lining the airway passages, larynx, and trachea, trauma and injury can be produced to the patient by the hard, open, bevel tip of endotracheal tubes. The use of an inflated balloon protruding from and filling the distal tip of the endotracheal tube during the process of intubation prevents trauma and injury.

Conventional malleable metal stylets can be preformed together with the endotracheal tube at their distal tips to a "J" shape. This often aids in intubating anteriorly or malpositioned displaced larynxes. No protection is afforded to the mucous membranes and anatomical structures, however, from the hard, open-ended bevel tip of the endotracheal tube. Protrusion of the hard, pointed stylet tip beyond the confines of the endotracheal tube distal tip may occur and cause serious injury, particularly during the course of a difficult intubation. Misdirected intubation into the esophagus has often caused serious injury or perforation.

The combination of a malleable stylet with a balloon sheath at the distal portion allows for maximum directionality while affording maximum protection. These are the paramount objectives and purposes of this invention.

The present invention is directed to improvements in the intubation of catheters and endotracheal tubes and, especially, to the intubation of orotracheal tubes by means of a malleable but shape-retaining introducer tube coupled with an inflatable sheath.

A soft, inflatable introducer having a closed, rounded, distal-tipped sheath, is inserted into the open proximal end of and through a hollow, cylindrical catheter or endotracheal tube, with the distal-tipped sheath protruding partway beyond the open distal end of the catheter. The distal-tipped sheath is inflated, prior to intubation, to a diameter equal to or slightly larger than the outer diameter of the catheter. Both catheter and introducer are intubated into and through the passageway of the patient. The inflated sheath serves not only as a guide but also as a soft and flexible opener or enlarger of the sensitive membranes within the passageway, thereby enabling the catheter to better and more safely penetrate and negotiate the varied shapes, obstacles, or bends encountered. After the catheter has been successfully intubated within the passageway through the larynx and into the trachea, for example, the distal-tipped sheath is deflated and the introducer is withdrawn.

SUMMARY OF THE INVENTION

The present invention resides in the use of malleable tubing in forming the connection between the distal inflatable tip of the introducer and its proximal end. Generally, ductile metals such as aluminum and copper may be used to form the hollow tubes that achieve such introducer rods. Similarly malleable metals, alloys, or other substances may also be used so long as they can be entirely sterilized for use in the operating theater and intimate patient contact.

Previously, only flexible and non-shape-retaining materials such as latex or other rubber, polyvinyl chloride, or other medically approved tubing have been used in order to form the hollow cylindrical tube that allows communication through the catheter between the proximal introducer end available to the physician and the distal introducer end intubated into the patient. While the use of such flexible introducers allowed for easier intubation with less trauma such as oropharyngeal bleeding or epistaxis; anomalous structures and anatomical variants such as an anteriorly positioned larynx could have prevented intubation entirely or allowed such intubation only with trauma to the patient. The inherent flexibility of both the catheter and the introducer tube prevented the physician from having any significant directional control over the end tip of the catheter with its introducer. This would sometimes limit introducer applicability for successful intubation.

Use of a rigid introducer tube is entirely inadequate as it cannot conform to the patient's internal contours. Particularly, the bends, curves, and other articulations present within the nasal and oral cavities and associated structures require that a catheter find clear passage there-through with as little obstruction as possible.